

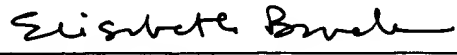
1

If there is any fee due in connection with the filing of this Statement, please charge the
fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 23, 2006

By: 
Elisabeth Jaffe Barek
Reg. No. 46,797

Copies of the listed foreign and non-patent literature documents are enclosed. Copies of the U.S. patents and patent publications are not enclosed.

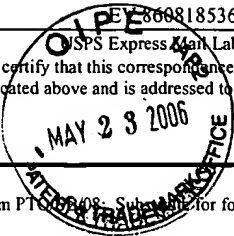
The United States Court of Appeals for the Federal Circuit held in *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 66 U.S.P.Q.2d 1801 (Fed. Cir. 2003), that an “adverse decision” by another examiner may meet the materiality standard under the amended Rule 56, and thus, Applicant should disclose prior rejections of “substantially similar claim[s]” to the Office. Accordingly, although Applicant is not representing that the Office Actions in the co-pending applications are material to the present application and is not admitting that any of the other claims are substantially similar, out of an abundance of caution, Applicant has listed the substantive Office Actions filed in co-pending applications on the enclosed Form PTO/SB/08 and has enclosed copies of those documents, as well.

Applicant respectfully requests that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the enclosed form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute “prior art.” If the Examiner applies any of the documents as prior art against any claims in the application and Applicant determines that the cited documents do not constitute “prior art” under United States law, Applicant reserves the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the claimed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

CERTIFICATE UNDER 37 CFR § 1.10 OF MAILING BY "EXPRESS MAIL"



May 23, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Services "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to the Mail Stop Addressee/Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Cheryl L. Franke
Cheryl L. Franke

IDS Form PTO 609, Sub-Form for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application No.	09/986,509
Filing Date	November 9, 2001
First Named Inventor	Graham E. KELLY
Art Unit	1616
Examiner Name	Edward J. WEBMAN
Attorney Docket Number	07579.0006-01000


U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

Examiner Initials	Cite No.	Document Number	Issue or Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code (if known)			
		US 2002/0198248 A1	12-26-2002	Kelly et al.	
		US 2003/0018060 A1	01-23-2003	Kelly et al.	
		US 2003/0059384 A1	03-27-2003	Kelly et al.	
		US 2003/0078214 A1	04-24-2003	Kelly	
		US 2003/0157225 A1	08-21-2003	Husband et al.	
		US 2003/0219499 A1	11-27-2003	Kelly et al.	
		US 2004/0048812 A1	03-11-2004	Kelly	
		US 2004/0072765 A1	04-15-2004	Kelly et al.	
		US 2004/0106561 A1	06-03-2004	Kelly	
		US 2004/0116498 A1	06-17-2004	Husband	
		US 2004/0147551 A1	07-29-2004	Heaton et al.	
		US 2004/0152761 A1	08-05-2004	Heaton et al.	
		US 2004/0170713 A1	09-02-2004	Kelly	
		US 2005/0036962 A1	02-17-2005	Kelly et al.	
		US 2005/0059616 A1	03-17-2005	Kelly et al.	
		US 2005/0143588 A1	06-30-2005	Heaton et al.	
		US 4,379,177	04-05-1983	McCoy et al.	
		US 5,153,230	10-06-1992	Jaffery	
		US 5,424,331	06-13-1995	Shlyankevich	
		US 5,498,631 B1	03-03-1998	Gorbach et al.	
		US 5,523,087	06-04-1996	Shlyankevich	
		US 5,637,598	06-10-1997	Grese	
		US 5,855,892	01-05-1999	Potter et al.	
		US 6,033,714	03-07-2000	Gugger et al.	
		US 6,060,070	05-09-2000	Gorbach	

Examiner
Signature

Date
Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



IDS Form PTO/SB/08: Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application No.	09/986,509
Filing Date	November 9, 2001
First Named Inventor	Graham E. KELLY
Art Unit	1616
Examiner Name	Edward J. WEBMAN
Attorney Docket Number	07579.0006-01000

Sheet

2

of

4

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS					
		US 6,235,773 B1	05-22-2001	Bissett	
		US 6,599,536 B1	07-29-2003	Kelly et al.	
		US 6,642,212 B1	11-04-2003	Kelly	
		US 6,649,648 B1	11-18-2003	Kelly et al.	
		US 6,987,098 B2	01-17-2006	Kelly	
		US 7,033,621 B1	04-25-2006	Kelly et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code Number Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation
		AU 1997-40034 B2	03-19-1998	Novogen Research Pty. Ltd.		
		EP 0 412 211 A1	02-13-1991	Therapeutical Systems Corp.		
		WO 98/08503 A1	03-05-1998	Novogen Research Pty. Ltd.		
		WO 98/50026 A1	11-12-1998	Novogen, Inc.		
		WO 99/11260 A1	03-11-1999	Pfizer, Inc.		
		WO 99/11263 A1	03-11-1999	Pfizer Products Inc.		
		WO 99/36050 A1	07-22-1999	Novogen Research Pty. Ltd.		
		WO 99/49862 A1	10-07-1999	The University of Mississippi		
		WO 00/16759 A2	03-30-2000	Schnyder		
		WO 00/49009 A1	08-24-2000	Novogen Research Pty. Ltd.		
		WO 00/54753 A2	09-21-2000	Johnson & Johnson Consumer Companies, Inc.		
		WO 00/64438 A1	11-02-2000	Novogen Research Pty. Ltd.		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation
		BABER, R. et al., "The effect of an isoflavone dietary supplement (Rimostil™) on serum lipids, forearm bone density and endometrial thickness in post-menopausal women," <i>10th Annual Meeting of the North American Menopause Society</i> , New York, 4 pages (1999).	
		CASWELL, A. (Ed.) "Hypolipidaemic agents," <i>MIMS Annual</i> , 23rd Edition, pp. 2f-152 to 2f-168, Tien Wah Press, Singapore (1999).	
		CHAN, K. et al., "Inhibitors of hydroxymethylglutaryl-coenzyme A reductase and risk of fracture among older women," <i>Lancet</i> 355:2185-2188 (2000).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application No.	09/986,509
				Filing Date	November 9, 2001
				First Named Inventor	Graham E. KELLY
				Art Unit	1616
				Examiner Name	Edward J. WEBMAN
Sheet	3	of	4	Attorney Docket Number	07579.0006-01000

NON PATENT LITERATURE DOCUMENTS			
		CHANG, Y-C. et al., "Microwave-mediated synthesis of anticarcinogenic isoflavones from soybeans," <i>J Agric. Food Chem.</i> 42:1869-1871 (1994).	
		Chicago Center for Clinical Research, Company Press Release, March 13, 2000, "Chicago Center for Clinical Research study suggests new, more effective way to treat older women with high cholesterol," 1 page.	
		CLIFTON-BLIGH, P. et al., "The effect of isoflavones extracted from red clover (Rimostil™) on lipid and bone metabolism," <i>Menopause</i> 8(4):259-265 (2001).	
		DÖREN, M. et al., "Identification and treatment of postmenopausal women at risk for the development of osteoporosis," <i>Intl. J. Clin. Pharmacology, Therapy and Toxicology</i> 30(11):431-433 (1992).	
		DUBEY, R. et al., "Phytoestrogens inhibit growth and MAP kinase activity in human aortic smooth muscle cells," <i>Hypertension</i> 33(Part II):177-182 (1999).	
		EVANS, D. et al., "Ovarian cancer family and prophylactic choices," <i>J. Medical Genetics</i> , 29:416-418 (1992).	
		GOH, J. et al., "Postmenopausal endometrioma and hormonal replacement therapy," <i>Aust. NZ J. Obstet. Gynaecol.</i> 32(4):384-385 (1992).	
		GOLDMAN, L. et al., "Cost and health implications of cholesterol lowering," <i>Circulation</i> 85:1960-1968 (1992).	
		GRAHAM, T., "Flavonoid and isoflavonoid distribution in developing soybean seedling tissues and in seed and root exudates," <i>Plant Physiol.</i> 95:594-603 (1991).	
		GRODSTEIN, F. et al., "Postmenopausal hormone use and cholecystectomy in a large prospective study," <i>Obstet. Gynecol.</i> 83(1):5-11 (1994).	
		GUGGOLZ, J. et al., "Detection of daidzein, formononetin, genistein, and biochanin A in forages," <i>Agr. Food Chem.</i> 9(4):330-332 (1961).	
		HEBERT, P. et al., "Cholesterol lowering with statin drugs, risk of stroke, and total mortality. An overview of randomized trials," <i>JAMA</i> 278(4):313-321 (1997).	
		HULLEY, S. et al., "Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women," <i>JAMA</i> 280(7):605-613 (1998).	
		KELLY, S. et al., "Protein tyrosine phosphorylation mediates TNF-induced endothelial-neutrophil adhesion in vitro," <i>Am. J. Physiol.</i> 274 (<i>Heart Circ. Physiol.</i> 43):H513-H519 (1998).	
		MAY, M. et al., "Effects of protein tyrosine kinase inhibitors on cytokine-induced adhesion molecule expression by human umbilical vein endothelial cells," <i>Br. J. Pharmacol.</i> 118:1761-1771 (1996).	
		NESTEL, P. et al., "Isoflavones from red clover improves systemic arterial compliance but not plasma lipids in menopausal women," <i>J. Clin. Endocrinology and Metabolism</i> 84(3):895-898 (1999).	
		PALMETSHOFER, A. et al., "α-Galactosyl epitope-mediated activation of porcine aortic endothelial cells," <i>Transplantation</i> 65(7):971-978 (1998).	
		PANCHAGNULA, R. et al., "Transdermal iontophoresis revisited," <i>Curr. Opin. Chem. Biol.</i> 4:468-473 (2000).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

IDS Form PTO/SB/08: Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				<i>Application No.</i>	09/986,509
				<i>Filing Date</i>	November 9, 2001
				<i>First Named Inventor</i>	Graham E. KELLY
				<i>Art Unit</i>	1616
				<i>Examiner Name</i>	Edward J. WEBMAN
Sheet	4	of	4	<i>Attorney Docket Number</i>	07579.0006-01000

NON PATENT LITERATURE DOCUMENTS		
	PARFITT, K. (Ed.), <u>Martindale, The complete drug reference</u> , 32nd Edition, Pharmaceutical Press, London, Table of Contents, p. vi (1999).	
	PEDERSON, T. et al., "Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)," <i>The Lancet</i> 344:1383-1389 (1994).	
	SACKS, F. et al., "The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels," <i>The New England Journal of Medicine</i> 335(14):1001-1009 (1996).	
	SAMMAN, S. et al., "The effect of supplementation with isoflavones on plasma lipids and oxidisability of low density lipoprotein in premenopausal women," <i>Atherosclerosis</i> 147:277-283 (1999).	
	SBAROUNI, E. et al., "The effect of hormone replacement therapy alone and in combination with simvastatin on plasma lipids of hypercholesterolemic postmenopausal women with coronary artery disease," <i>J. Am. Coll. Cardiol.</i> 32:1244-1250 (1998).	
	STAMPFER, M. et al., "A prospective study of cholesterol, apolipoproteins, and the risk of myocardial infarction," <i>The New England Journal of Medicine</i> 325(6):373-381 (1991).	
	TAMURA, S. et al., "Chemical studies on 'clover sickness;' Part I. Isolation and structural elucidation of two new isoflavonoids in red clover," <i>Agr. Biol. Chem.</i> 33(3):391-397 (1969).	
	WEI, H. et al., "Antioxidant and antipromotional effects of the soybean isoflavone genistein," <i>P.S.E.B.M.</i> 208:124-130 (1995).	
	WEIDENBÖRNER, M. et al., "Antifungal activity of isoflavonoids in different reduced stages on <i>Rhizoctonia solani</i> and <i>Sclerotium rolfsii</i> ," <i>Phytochemistry</i> 29(3):801-803 (1990).	
	WEINBERG, D. et al., "Identification and quantification of anticarcinogens in garlic extract and licorice root extract powder," <i>J. High Resolution Chromatography</i> 15:641-654 (1992).	
	Amendment filed in U.S. Patent Application No. 10/600,004 on May 16, 2006 (Attorney Docket No. 07579-0015-01000).	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.